THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 13

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

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Ex parte CHARLES G. MIYADA,
ARTHUR C. SWITCHENKO, MELANIE W. QUONG
and MAN-YING L. WONG

_____

Appeal No. 1997-3378
Application 08/487,946

_____

ON BRIEF

_____

Before WILLIAM F. SMITH, SCHEINER, and MILLS, Administrative Patent Judges.

MILLS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. §134 from the examiner's final rejection of claims 5-9, 40[1] [sic 39], 41 and 42. Claims 41 and 42 have been withdrawn from consideration by the examiner in Paper No. 7, mailed July 11, 1996.

[1] The final rejection rejects claims 5-9, 40, however, appellants point out that claim 40 was canceled at the time of filing of the present application and believe that the rejection is applied to claim 39 instead of claim 40. Appeal Brief, page 2. See also Paper No. 4, page 2, referencing claim 39.

We reverse.

Claim 5 is illustrative of the claims on appeal and reads as follows:

5. A method for determining D-arabinitol, which method comprises the steps of:

providing in combination (1) a medium suspected of containing D-arabinitol and (2) a D-arabinitol dehyrogenase enzyme, said enzyme being capable of catalyzing the oxidation of D-arabinitol and substantially incapable of catalyzing the oxidation of D-mannitol, and

examining said medium for a product produced as a result of said oxidation of said D-arabinitol.

OPINION

In reaching our decision in this appeal, we have given careful consideration to the appellants' specification and claims, to the applied prior art references, and to the respective positions articulated by the appellants and the examiner.

Rather than reiterate the conflicting viewpoints advanced by the examiner and the appellants regarding the above-noted rejection, we make reference to the examiner's answer (Paper No. 12, February 26, 1997) for the examiner's complete reasoning in support of the rejection, and to the appellants' brief (Paper No. 10, December 16, 1996) for the appellants' arguments thereagainst. As a consequence of our review, we make the determinations which follow.

DECISION ON APPEAL

Claims 5-9 and 39 stand rejected under 35 U.S.C. § 112, first paragraph for failing to provide an enabling disclosure. An analysis of whether the claims under appeal are

supported by an enabling disclosure requires a determination of whether that disclosure contained sufficient information regarding the subject matter of the appealed claims as to enable one skilled in the pertinent art to make and use the claimed invention. In order to establish a prima facie case of lack of enablement, the examiner must provide a reasonable explanation as to why the scope of protection provided by a claim is not adequately enabled by the disclosure. In re Wright, 999 F.2d 1557, 1561-62, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); In re Morehouse, 545 F.2d 162, 165, 192 USPQ 29, 32 (CCPA 1976). The threshold step in resolving this issue is to determine whether the examiner has met his burden of proof by advancing acceptable reasoning inconsistent with enablement.

Factors to be considered by the examiner in determining whether a disclosure would require undue experimentation have been summarized by the board in Ex parte Forman, 230 USPO 546, 547 (Bd. Pat. App. & Int. 1986). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. (footnote omitted). In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404, (Fed. Cir. 1988).

In our opinion, the examiner has failed to set forth a prima facie case of lack of enablement. It is the examiner's position that the disclosure is only enabling for claims directed to a method employing the particular isolated D-arabinitol dehydrogenase

(DADH) enzyme, isolated from a specific Candida species, as disclosed in the specification. The examiner suggests that the appellants have not described or characterized any other enzymes with these characteristics nor have they demonstrated, convincingly, how the skilled artisan would find or isolate or use other enzymes. Examiner's Answer pages 2-3.

Such a broad allegation by the examiner that the disclosure is speculative, coupled with a recitation of various difficulties which might be encountered in practice, is not sufficient basis for requiring proof of operability. In re Chilowsky, 229 F.2d 457, 463, 108 USPO 321, 326 (CCPA 1956). It does not reasonably appear that the examiner has advanced acceptable reasoning, specific argument or other form of evidence which would support the proposition that one of ordinary skill in the art would find the specification inconsistent with enablement. The examiner has not provided a reasoned analysis indicating that the factors set forth in Ex Parte Forman have been considered in a meaningful way to establish a prima facie case of enablement.

In considering the enablement rejection before us for review, we find the following passage from PPG Indus., Inc. v. Guardian Indus. Corp., 75 F.3d 1558, 1564, 37 USPQ2d 1618, 1623 (Fed. Cir. 1996) to be instructive.

> In unpredictable art areas, this court has refused to find broad generic claims enabled by specifications that demonstrate the enablement of only one or a few embodiments and do not demonstrate with reasonable specificity how to make and use other potential embodiments across the full scope of the claim. See, e.g., In re Goodman, 11 F.3d 1046, 1050-52, 29 USPQ2d 2010, 2013-15 (Fed. Cir. 1993); Amgen, Inc. v. Chugai Pharmaceutical Co., 927 F.2d. 1200, 1212-14, 18 USPQ2d 1016, 1026-28 (Fed. Cir.), cert.

> denied, 502 U.S. 856 (1991); In re Vaeck, 947 F.2d at 496, 20 USPQ2d at 1445. Enablement is lacking in those cases, the court has explained, because the undescribed embodiments cannot be made, based on the disclosure in the specification, without undue experimentation. But the question of undue experimentation is a matter of degree. The fact that some experimentation is necessary does not preclude enablement; what is required is that the amount of experimentation "must not be unduly extensive." Atlas Powder Co., v. E.I. DuPont De Nemours & Co., 750 F.2d 1569, 1576, 224 USPQ 409, 413 (Fed. Cir. 1984). The Patent and Trademark Office Board of Appeals summarized the point well when it stated:
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> > The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the invention claimed. Ex parte Jackson, 217 USPQ 804, 807 (1982).

In addition, the examiner has failed to fully address the rebuttal argument put forth by appellants. Appellants indicate that the specification instructs one skilled in the art that the DADH of the present invention can be isolated from members of the genus Candida, for example Candida tropicalis and Candida shehatae. Page 11, lines 13-14. The appellants also argue that the monoclonal antibodies described in the specification reasonably enable the skilled artisan to screen for and isolate a specific DADH from any source, and suggests that DADH from other species can be identified and isolated by determining whether the DADH enzyme can bind to at least one of the present monoclonal antibodies. Thus, it would appear that the experimentation required to practice the claimed method within the claim scope would not have amounted to more than simple screening. See, Tabuchi v. Nubel, 559 F.2d 1183, 1186, 194 USPQ 521, 523 (CCPA 1977); (Claim to a

method of producing citric acid comprising inoculating a citric acid accumulating strain and hydrocarbon assimilating strain of a yeast belonging to the genus Candida, was enabled by specification generally directed to the genus Candida, with no deposited Candida strains).

The appellants submit that the specific monoclonal antibodies of the present invention can be used by the skilled artisan to isolate the claimed DADHs without undue experimentation. The examiner has failed to establish, or put forth contrary fact or argument in view of appellants rebuttal argument, why one of ordinary skill in the art would require undue experimentation to practice the claimed invention. Moreover, it would reasonably appear that all that is required for one of ordinary skill in the art to practice the claimed method within the scope of the claim, is a single DADH enzyme possessing the claimed characteristics, which is clearly enabled by the specification at page 32, Table 1. On this basis, we hold that the examiner has not established a prima facie case of lack of enablement.

CONCLUSION

The rejection of the claims under 35 U.S.C. § 112, first paragraph is reversed.

REVERSED

WILLIAM F. SMITH Administrative Patent Judge	))))) BOARD OF PATENT
TONI R. SCHEINER Administrative Patent Judge	)) APPEALS AND)) INTERFERENCES
DEMETRA J. MILLS Administrative Patent Judge	))

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